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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,225	05/04/2001	Kenichiro Shiroyama	Q64175	6389
65565	7590	04/01/2010	EXAMINER	
SUGHRUE-265550 2100 PENNSYLVANIA AVE. NW WASHINGTON, DC 20037-3213			CHANNAVAJALA, LAKSHMI SARADA	
ART UNIT		PAPER NUMBER		
1611				
NOTIFICATION DATE		DELIVERY MODE		
04/01/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 09/848,225	<b>Applicant(s)</b> SHIROYAMA ET AL.
	<b>Examiner</b> Lakshmi S. Channavajala	<b>Art Unit</b> 1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

#### **Status**

1) Responsive to communication(s) filed on 12 January 2010.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 7 and 12-29 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 7 and 12-29 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement (Form PTO-1449)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

Receipt of amendment and response dated 1-12-10 is acknowledged.

Claims 7 and 12-29 are pending in the instant application.

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1-12-09 has been entered.

***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 7 and 12-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,355,232 to Kaneko et al and EP 092852 (EP 252 submitted on PTO-1449 dated 1-27-03) in view of US 5,294,444 to Nakamura et al or Nakamura in view of Kaneko and EP 092852, and further in view of either one of JP-A-04-193814 ('814) or JP 63-192703 ('703).

4. The newly cited JP '814 and JP '703 references have been submitted by applicants on IDS dated 5-13-09.

5. Nakamura teaches a transparent or semi-transparent cosmetic composition comprising an amphipathic lipid, nonionic surfactant, ionic surfactant and an aqueous

medium (abstract, col. 2, lines 1-18). Nakamura teaches the non-ionic surfactant of instant claim 13 (col. 3, lines 1-5 & tables 2 and 3), cholesterol and fatty acids (table 2). The amounts of ceramides, non-ionic surfactants, fatty acids and cholesterol in the composition taught by Nakamura are within the instant claimed ratios table 2). With respect to the claimed method step of mixing lipid composition while heating at 80 -120 degrees C and heating water at 80 to 100 degrees C, Nakamura teaches that the components of table 3 were mixed and melted at a temperature of 85- 90 degrees C (within the heating temperature of instant claims), followed by addition of hot water (Col. 4, lines 51-55). While Nakamura fails to state the specific temperature of water, absent evidence to the contrary, the term "hot water" includes boiling water, which is 100 degrees C or water as hot as 80 C. Nakamura also teaches that the compositions do not irritate the skin, as claimed (col. 1, lines 65-68).

6. Nakamura teaches ceramides, glyceroceramides and ceramide derivatives, but does not teach the ceramides having the structural formula of instant claims. Nakamura fails to teach the claimed optically active compounds.

7. Kaneko teach skin and hair protective compositions comprising erythro (2S, 3R) type of ceramides having the structural formula I -VI (col. 2, lines 15 through col. 3, lines 57). In particular, the ceramides of structural formula I meets the claimed structure II of claim 15. Kaneko also suggests a combination of amphipathic surfactants such as fatty acids, fatty alcohols etc., and cholesterol or a phytosterol, in the composition (col. 3, lines 58 through col. 4, lines 28).

8. EP '852 teaches hair care compositions comprising at least one (2S,2R)-2-acylaminoalkane-1,3-diol compounds of formula I, where the variables R1 and R2 read on the variables described in the instant formula I of claim 7. In particular, the compounds that are claimed in the instant claims 18 and 21-26 are described in the compounds on page 7 of EP 852. EP also recognizes the ceramides compounds for retaining moisture and as a skin barrier ([0010]) in addition to using them for increasing the hair strength.

9. Thus, all three references (Nakamura, EP and Kaneko) recognize the ceramides for their improved barrier functions in skin and hair applications.

10. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to replace the ceramides of Nakamura, with the optically active ceramides of Kaneko and that of EP 252 because Kaneko as well as EP 252 teach that the optically active ceramides exert remarkable water-barrier functions in skin protection compositions, as opposed to the racemates and significantly higher water holding capacity than racemates and pseudoceramides (col. 1, lines 59-67 and col. 8, lines 10-15) and improve hair strength. Alternatively, a skilled artisan would have been able to employ the method of preparing transparent lipid compositions such as pseudoceramides of Nakamura in preparing the composition of Kaneko because Nakamura suggests that the compositions are stable and non-irritating.

11. Thus, a skilled artisan would have expected that the ceramides of Kaneko to function better than the ceramides or pseudoceramides of Nakamura. While Kaneko fails to teach the specific ceramides of claims 18-20, in the absence of establishing an

unexpected result with respect to the specific active ceramides taught by Kaneko, one of an ordinary skill in the art at the time of the instant invention was made would understand from the teachings of Kaneko and EP that the 2S, 3R type of ceramides (optically active) are significantly more efficient in their skin moisturizing effect than the racemates and pseudoceramides because Kaneko teaches that the water restraining capacity of optically active ceramides is higher than the other ceramides (col. 8, lines 18-56).

12. With respect to the new limitation "cosmetic additive", all of the references cited teach cosmetic compositions and thus meet the limitation. It is unclear how instant composition can be an additive when the ceramides of the instant application are also taught for the same function i.e., protection of stratum corneum.

13. With respect to the limitation "free of ionic surface active agent", applicants agree that Kaneko does not require surface active agent, which meets the claimed proviso limitation.

14. On the other hand, each of the newly added JP '814 and JP '703 references, teach ceramide compositions.

15. JP '814 shows a transparent cosmetic containing an amphipathic lipid, a nonionic surfactant and an aqueous medium (Claims) for the purpose of compounding an amphipathic lipid in a transparent state in a stable manner and of preparing a cosmetic having no risk of skin irritation (upper left column, page 2), exemplified ceramide as the amphipathic medium (upper right column, page 2), polyoxyethylene castor oil as the nonionic surfactant (upper left column, page 3) and water or a combination of water with

water-soluble alcohols such as glycerin or 1,3- butanediol as the aqueous medium (lower left and lower right columns, page 3).

16. JP 703 discloses an oil-in-water type emulsified cosmetic in Example 4 in which 5.0% by weight of ceramide (bovine brain ceramide), stearic acid, polyoxyethylene (60) hydrogenated castor oil, glyceryl ether and water are compounded. Although said document does not teach that the composition in the Example is transparent, there is a high possibility that it is a transparent composition since the composition of the document is identical with that of the present application. Particularly in Examples 22 to 28, there is disclosed a lotion which contains an amide derivative, stearic acid/palmitic acid, polyoxyethylene hydrogenated castor oil, glycerin, cholesterol and water.

17. Thus, it would have been obvious for a skilled artisan at the time of the instant invention was made to anionic surfactants of Nakamura in the preparation of transparent stable composition because the references of JP 703 and JP 814 teach the preparation of ceramide composition without the need of anionic surfactants. Furthermore, applicants have not shown any unexpected advantages of excluding ionic surfactant from the composition. On the other hand, the instant specification clearly states that one can employ anionic surfactants (including those described by Nakamura or EP 852).

***Response to Arguments***

18. Applicant's arguments filed 1-12-10 have been fully considered but they are not persuasive.

19. Applicants' arguments with respect to the teachings of Knoll have been considered but are moot in light of the newly added JP references of record.

20. Applicants argue that none of the cited references, either taken alone or in combination, disclose or render obvious the features of the presently claimed invention i.e., a clear aqueous ceramide. Applicants admit that the primary reference Kaneko does not require an ionic surfactant (see the table on page 12 of the response). However, they argue that Kaneko does not teach transparent and instead only teaches a soluble ceramide. However, the argument is not persuasive because the rejection relies on the teachings of Nakamura for the process of preparing. Applicants have not provided any evidence that the process of Nakamura substituted with the ceramides of Kaneko does not yield transparent solutions. The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). The argument that Kaneko fails to teach all the limitations is not persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The argument that none of Nakamura, Kaneko or EP '852 render the instant claim 7 obvious, the argument is not persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

21. With respect to the new limitation "cosmetic additive", all of the references cited teach cosmetic compositions and thus meet the limitation. It is unclear how instant composition can be an additive when the ceramides of the instant application are also taught for the same function i.e., protection of stratum corneum. While on one hand applicants argue that Kaneko teaches a lipid composition which is to be blended into a final product, instant claims do not exclude employing the instant composition in to a final composition. Further, the newly added limitation cosmetic additive" even supports the use of the instant composition in to a final cosmetic composition by blending it with other cosmetic ingredients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/  
Primary Examiner, Art Unit 1611  
March 28, 2010